

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

02/480,389

01/11/00

BOMAN

B

CATX-N

024988

LEONA L LAUDER

369 PINE STREET

SUITE 610

SAN FRANCISCO CA 94104-3313

HM12/0717

EXAMINER

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/480,389

Applicant(s)
Bowman, B.

Examiner
Anne Holleran

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 26, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-28, and 31-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-6, 9-28, and 31-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. The amendment filed April 26, 2001 (Paper No. 11) is acknowledged. Claims 7, 8, 29 and 30 were canceled. Claims 49-54 were added.

Claims 1-6, 9-28 and 31-54 are pending.

2. Applicant's election with traverse of Group II in Paper No. 11, filed April 26, 2001, is acknowledged. Upon reconsideration, the restriction requirement between Groups I (claims 1-6, 9-28 and 31-54) and II (claims 1-6, 9-28 and 31-54) is removed. Upon reconsideration, the species election requirement from the species of biological samples recited in claim 9 and from the species of detection methods recited in claim 22 is removed. The species election requirement between methods of detection of germline and detection of somatic mutations is removed in light of the amendment to the claims limiting the methods to diseases or disease susceptibility associated with germline mutation.

3. Upon further consideration, claims 1-6, 9-28 and 31-54 are subject to a second restriction requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 9-23, and 45-53, drawn to methods for detecting a disease or a disease susceptibility trait associated with a germline mutation in one subject gene, classified in class 435, subclass 7.1.
- II. Claims 24-28, 31-44 and 54, drawn to methods for detecting a disease or a disease susceptibility trait associated with a germline mutation in one of two or more subject genes, classified in class 435, subclass 7.1.

4. The inventions are distinct, each from the other, for the following reasons:

Inventions I and II are drawn to distinct methods because the methods of group I require different steps than the methods of group II. The methods of group I require the identification of one subject gene, whereas the methods of group II require the identification of at least two subject genes. Furthermore, the calculation of the ratio of amount of wild-type protein in group I is with reference to standard housekeeping proteins, whereas the calculation of the ratio of amount of wild-type protein in group II is between one of the subject genes and any number of other subject genes. Thus, the calculation of the ratios yield different information in the methods of group I than does the calculation of the ratio in the methods of group II.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Election of species:

5. In group I, Claims 1-6 and 9-15, 17, 22 and 23 are generic to a plurality of disclosed patentably distinct species of subject genes, comprising ATM, APC, BRCA1, BRCA2, CFTR, c-myc, dystrophin, E-cadherin, EMD, FAA, IDS, MLH1, MSH2, MSH6, NF1, NF2, p16, PKD1, PKD2, PMS1, PMS2, PTCH, TGFBR2, and VHL. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In group II, Claims 24-28, 31-37, 39, 43, 44 and 52 are generic to a plurality of disclosed patentably distinct species of subject genes, comprising ATM, APC, BRCA1, BRCA2, CFTR, c-myc, dystrophin, E-cadherin, EMD, FAA, IDS, MLH1, MSH2, MSH6, NF1, NF2, p16, PKD1, PKD2, PMS1, PMS2, PTCH, TGFBR2, and VHL. Applicant is required under 35 U.S.C. 121 to elect two disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Application/Control Number: 09/480,389
Art Unit: 1642

Page 5

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

AH

Anne L. Holleran
Patent Examiner
July 15, 2001

AC

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600